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## NOTICE OF ALLOWANCE AND FEE(S) DUE

23117 7590 05/23/2003

NIXON & VANDERHYE, PC  
1100 N GLEBE ROAD  
8TH FLOOR  
ARLINGTON, VA 22201-4714

EXAMINER

TUNG, JOYCE

ART UNIT

CLASS-SUBCLASS

1637

435-110000

DATE MAILED: 05/23/2003

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/023,483	02/13/1998	JEFFREY A. HEROUX	2528-2	6994

TITLE OF INVENTION: ASSAY METHODS FOR NUCLEIC ACID IN A SAMPLE

APPLN. TYPE	SMALL ENTITY	ISSUE FEE	PUBLICATION FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	YES	\$650	\$300	\$950	08/25/2003

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE REFLECTS A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE APPLIED IN THIS APPLICATION. THE PTOL-85B (OR AN EQUIVALENT) MUST BE RETURNED WITHIN THIS PERIOD EVEN IF NO FEE IS DUE OR THE APPLICATION WILL BE REGARDED AS ABANDONED.

### HOW TO REPLY TO THIS NOTICE:

#### I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status is changed, pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above and notify the United States Patent and Trademark Office of the change in status, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check the box below and enclose the PUBLICATION FEE and 1/2 the ISSUE FEE shown above.

☐ Applicant claims SMALL ENTITY status.  
See 37 CFR 1.27.

II. PART B - FEE(S) TRANSMITTAL should be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). Even if the fee(s) have already been paid, Part B - Fee(s) Transmittal should be completed and returned. If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER:** Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

# **PART B - FEE(S) TRANSMITTAL**

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE  
Commissioner for Patents  
Alexandria, Virginia 22313-1450  
Fax (703)746-4000**

**INSTRUCTIONS:** This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 4 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

**CURRENT CORRESPONDENCE ADDRESS** (Note: Legibly mark-up with any corrections or use Block 1)

23117 7590 05/23/2003

**NIXON & VANDERHYE, PC**  
1100 N GLEBE ROAD  
8TH FLOOR  
ARLINGTON, VA 22201-4714

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

## **Certificate of Mailing or Transmission**

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Box Issue Fee address above, or being facsimile transmitted to the USPTO, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

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nonprovisional	YES	\$650	\$300	\$950	08/25/2003

EXAMINER	ART UNIT	CLASS-SUBCLASS
TUNG, JOYCE	1637	435-110000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.

☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a **Customer Number** is required.

2. For printing on the patent front page, list (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed.

1 \_\_\_\_\_  
2 \_\_\_\_\_  
3 \_\_\_\_\_

## **3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)**

**PLEASE NOTE:** Unless an assignee is identified below, no assignee data will appear on the patent. Inclusion of assignee data is only appropriate when an assignment has been previously submitted to the USPTO or is being submitted under separate cover. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) ☐ individual ☐ corporation or other private group entity ☐ government

4a. The following fee(s) are enclosed:

☐ Issue Fee

☐ Publication Fee

☐ Advance Order - # of Copies \_\_\_\_\_

4b. Payment of Fee(s):

☐ A check in the amount of the fee(s) is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Commissioner is hereby authorized by charge the required fee(s), or credit any overpayment, to Deposit Account Number \_\_\_\_\_ (enclose an extra copy of this form).

Commissioner for Patents is requested to apply the Issue Fee and Publication Fee (if any) or to re-apply any previously paid issue fee to the application identified above.

(Authorized Signature)

(Date)

**NOTE:** The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Alexandria, Virginia 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Alexandria, Virginia 22313-1450.**

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**TRANSMIT THIS FORM WITH FEE(S)**



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23117	7590	05/23/2003	EXAMINER	
NIXON & VANDERHYE, PC 1100 N GLEBE ROAD 8TH FLOOR ARLINGTON, VA 22201-4714			TUNG, JOYCE	
			ART UNIT	PAPER NUMBER
			1637	

DATE MAILED: 05/23/2003

## Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The patent term adjustment to date is 0 days. If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the term adjustment will be 0 days.

If a continued prosecution application (CPA) was filed in the above-identified application, the filing date that determines patent term adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) system. (<http://pair.uspto.gov>)

Any questions regarding the patent term extension or adjustment determination should be directed to the Office of Patent Legal Administration at (703)305-1383.



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NIXON & VANDERHYE, PC 1100 N GLEBE ROAD 8TH FLOOR ARLINGTON, VA 22201-4714 UNITED STATES			TUNG, JOYCE	
			ART UNIT	PAPER NUMBER
			1637	

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## Notice of Fee Increase on January 1, 2003

If a reply to a "Notice of Allowance and Fee(s) Due" is filed in the Office on or after January 1, 2003, then the amount due will be higher than that set forth in the "Notice of Allowance and Fee(s) Due" since there will be an increase in fees effective on January 1, 2003. See Revision of Patent and Trademark Fees for Fiscal Year 2003; Final Rule, 67 Fed. Reg. 70847, 70849 (November 27, 2002).

The current fee schedule is accessible from: <http://www.uspto.gov/main/howtofees.htm>.

If the issue fee paid is the amount shown on the "Notice of Allowance and Fee(s) Due," but not the correct amount in view of the fee increase, a "Notice to Pay Balance of Issue Fee" will be mailed to applicant. In order to avoid processing delays associated with mailing of a "Notice to Pay Balance of Issue Fee," if the response to the Notice of Allowance and Fee(s) due form is to be filed on or after January 1, 2003 (or mailed with a certificate of mailing on or after January 1, 2003), the issue fee paid should be the fee that is required at the time the fee is paid. If the issue fee was previously paid, and the response to the "Notice of Allowance and Fee(s) Due" includes a request to apply a previously-paid issue fee to the issue fee now due, then the difference between the issue fee amount at the time the response is filed and the previously paid issue fee should be paid. See Manual of Patent Examining Procedure, Section 1308.01 (Eighth Edition, August 2001).

Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at (703) 305-8283.

# Notice of Allowability

Application No.

09/023,483

Applicant(s)

Heroux et al.

Examiner

Joyce Tung

Art Unit

1637



--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course.

**THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 4/07/2003.
2. ☒ The allowed claim(s) is/are claims 1-33, 38-40, 62-74 and 80-92 (final claims 1-62).
3. ☐ The drawings filed on \_\_\_\_\_ are accepted by the Examiner.
4. ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
a) ☐ All b) ☐ Some\* c) ☐ None of the:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

5. ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
(a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS must be submitted.  
(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached  
1) ☐ hereto or 2) ☐ to Paper No. \_\_\_\_\_.  
(b) ☐ including changes required by the proposed drawing correction filed \_\_\_\_\_, which has been approved by the examiner.  
(c) ☐ including changes required by the attached Examiner's Amendment/Comment or in the Office action of Paper No. \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top margin (not the back) of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

- |  |  |
|--|--|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892)  | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                    | 4 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. <u>27</u> |
| 5 <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449), Paper No(s). _____          | 6 <input type="checkbox"/> Examiner's Amendment/Comment                                |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance    |
| 9 <input type="checkbox"/> Other   |  |

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### EXAMINER'S AMENDMENT

The after amendment filed 4/07/2003 has been entered. Following the entry of the amendment, claims 1-33, 38-40, 62-74 and 80-92 are allowable.

1. An extension of time under 37 CFR 1.136(a) is required in order to make an examiner's amendment which places this application in condition for allowance. During a telephone conversation conducted on 5/19/2003, requested an extension of time for one MONTH(S) and authorized the Commissioner to charge Deposit Account No. 14-1140 (2528-2, order number) the required fee of \$525.00 for this extension and authorized the following examiner's amendment. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

2. The ~~application~~ has been amended as follows:  
Cancel claims 34-37, 41-61, 75-79 and 93-97.

3. The following is an examiner's statement of reasons for allowance:

No prior art has been found teaching or suggesting a method for determining total nucleic acid in a sample. The method comprises mixing at least one random primer at least 4 nucleotides in length, having at least one detectable species, adding at least one nucleotide triphosphate at least one binding species, nucleic acid polymerase, incubating the mixture under conditions for the nucleic acid polymerase to be active, contacting the mixture with at least one solid phase, measuring total nucleic acid by measuring the total amount of the detectable species bound to the

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solid phase and determining whether the total nucleic acid in the sample is higher or lower than a threshold amount of contamination, wherein the threshold amount of contamination is equal to or less than 100pg. In addition, the method also is capable of detecting total nucleic acid in amounts as low as 5pg and detecting total DNA fragments shorter than 800 base pairs.

The closest prior art are the references of Hartley (5,043,272), Eberle et al. (5,413,906) and Merrick et al. (Biotech Forum Europe, 1992, vol. 9(6), pg. 398-403).

Hartley discloses a random amplification method and kit using a random oligonucleotide primer for a specific target nucleic acid detection.

Eberle et al. disclose a method for determining polymerase activity in which a detectable labeled mononucleotide triphosphate and immobilizable nucleoside triphosphate binding to a solid support are used (see column 2, lines 27-49, column 3, lines 50-68 and column 4, lines 1-21). However, Hartley and Eberle et al. do not teach or suggest the method which includes determining the total nucleic acid in the sample which is higher or lower than a threshold amount of contamination

Merrick et al. disclose threshold assays for monitoring the purification of a product, for example, the determination of total DNA as contaminant in recombinant products (See pg. 399, column 2 to pg. 400, column 1, first paragraph) and the assay was applied to quantify for picogram amounts of total DNA, such as 2 pg of DNA can be detected in a nonradioactive format (See pg. 399, column 2 to pg. 400, column 1, first paragraph).

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There is no motivation to combine these three references above to carry out the method for determining total nucleic acid in a sample involving determining whether the total nucleic acid in the sample is higher or lower than a threshold amount of contamination of 100pg because Merrick et al. do not suggest combining the threshold detection system with the amplification protocols of Hartley and Eberle et al. In fact the system of Merrick et al. will not work with the fragment of Hartley. The system of Eberle is highly specific for a selected DNA and would not improve the total DNA detection of Merrick et al. Therefore, there is no motivation to combine the references above to carry out the method for determining total nucleic acid in a sample involving determining whether the total nucleic acid in the sample is higher or lower than a threshold amount of contamination of 100pg.

4. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.



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5. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

May 19, 2003

  
JEFFREY SIEW  
PRIMARY EXAMINER

5/21/03